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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/556,897	04/20/2000	David J. Roach	MLD-038	5776

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EXAMINER

BEX, PATRICIA K

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/556,897

Applicant(s)

ROACH ET AL.

Examiner

P. Kathryn Bex

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 16-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- ☐ Interview Summary (PTO-413) Paper No(s). _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Examiner notes that Applicant did not make an affirmation of the election of Group I, claims 1-15. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-4, 7-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adourian *et al* (USP 6,207,031) in view of Harris *et al* (USP 5,096,670).

Adourian *et al* teach a method and apparatus for processing a sample of biomolecular analyte using a microchip substrate. The system utilizing a robot 36, 90 for moving a multi-tip pipetter 42 between a multi-well plate 34, 104 containing sample and a loading station 32

Art Unit: 1743

having a plurality of microchips 120 (Figs. 1, 4). The robot with attached pipetter delivers the sample to the sample ports 126 of the microchip. The pipetter inserts the pipette tips through a corresponding plurality of apertures 132 defined by a tip guide 124 positioned in overlying registry with the sample ports 126 of the microchip 120 (column 12, lines 35-61, Fig. 6).

Adourian *et al* teaches various embodiments of a microchip substrate defining a plurality of microchannels communicating between opposed cathode and anode ports, wherein each microchannel includes a sample port, waste port communicating across a segment of the microchannel adjacent to the cathode port (Figs 8A-11B). Additionally, Adourian *et al* teach optically scanning the separated samples with a CCD camera (column 16, lines 59- column 17, line 12). Adourian *et al* does not specifically recite the use of movable first or second tracks for holding the microchip substrate and microtiter plate, respectively.

Harris *et al* teach an automated patient sample analyzing instrument comprising a receiving substrate 46 mounted on a first frame 24 connected to a movable first track 370. The system includes a second track 20 with a microtiter plate 22 movably mounted thereon, a gantry positioned above the first and second tracks and carrying a multi-pipette 214 with two electrodes 264. The pipette controlled by motor 152, the first track controlled via motor 420 and the second track controlled by motor 225. Additionally, Harris *et al* disclose a platform positioned above the first track and having a detector 546 and wires located on it (column 18, line 23- column 19, line 18). Harris *et al* teach the system comprising a feedback mechanism comprising optical and mechanical position sensors located on both the first and second frames (column 9, line 50- column 14, line 25).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to include in the automated system of Adourian *et al*, the first and second moving tracks for holding the substrate and microtiter plate as taught by Harris *et al*, in order to increase throughput. Harris *et al* provides for continuous analysis since new microchip substrates and microtiter plates can be continually placed on the conveyors which move the microtiter plates and substrates downstream to the analyzers or waste receptacles (column 7, lines 20-39).

5. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adourian *et al* (USP 6,207,031) in view of Harris *et al* (USP 5,096,670), as applied to claim 4 above, and further in view of Simpson *et al* (USP 6,143,152).

Adourian *et al* and Harris *et al* as previously discussed above, fail to disclose a circuit board which has a first electrode terminal in communication with a first wire and sample terminals of the microchip substrate, a second electrode in communication with the cathode terminals of the microchip substrate, a third electrode terminal in communication with a waste terminal of the substrate and a fourth electrode in communication with an anode.

Simpson *et al* teach a microchip substrate having a plurality of microchannels 670, 671 communicating between opposed cathode 674 and anode ports 660, the microchip further defining for each microchannel a sample port 676, 678 and a waste port 672 communicating across a segment of the microchannel adjacent the cathode port (column 8, lines 13- 42, Figs. 9, 11-12). Each port being connected to a voltage source via wires to cause the electrophoretic separation. Such a chip is considered conventional and well known in the art for its high-speed separation, reproducibly, accurately and conveniently placed, robust and sensitive (column 2, lines 34-43).

Accordingly, it would have been obvious to one of ordinary skill in the art at the invention was made to have included in the method of Harris *et al* and Adourian *et al*, a microfabricated capillary electrophoresis chip and circuit board, as taught by Simpson *et al* in order to perform chemical analysis on the electrophoresis chip automatically, since such a chip is considered conventional and well known in the art for its high-speed separation, reproducibly, and its ability to be accurately and conveniently placed (column 2, lines 34-43).

Response to Arguments

6. Applicant's arguments filed February 13, 2003 have been fully considered but they are not persuasive. Applicant argues Adourian *et al* (USP 6,207,031), issued March 27, 2001, is not available as prior art because it has an effective filing date of September 14, 1998. Applicant correctly cites the effective filing date of the present application as July 02, 1998. Applicant argues that only subject matter that is prior art under 35 U.S.C 102 can be used to support a rejection under section 35 U.S.C. 103. Applicant then states the patent document must be available to the public to constitute prior art. Applicant contends that the date sufficiently available to the public is the date it is available as a 35 USC 102 (a) or (b) reference. Examiner does not agree, since the effective filing date of Adourian *et al* (USP 6,207,031) is the filing date of the provisional, filed on September 15, 1997. Moreover, the date sufficiently available to the public is the date it is available as a 35 USC 102 (a) or (b) or (e) reference. The Adourian *et al* (USP 6,207,031) reference clearly meets the requirements under 35 U.S.C. 102(e).

Conclusion

7. No claims allowed.

Art Unit: 1743


8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.


Jill Warden
Supervisory Patent Examiner
Technology Center 1700